Ramon Rossi Lopez – rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice)*
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co Lead/Liason Counsel for Plaintiffs
Doris and Alfred Jones

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA .....

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
DORIS JONES and ALFRED JONES, a married couple, Plaintiffs, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**JONES PLAINTIFFS' MEMORANDUM REGARDING RE *BOOKER* MOTIONS *IN LIMINE* THEY WISH TO RE-URGE** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

Pursuant to the Court's Minute Entry dated March 29, 2018, [Doc. 10582], Plaintiff Doris Jones re-urges all motions *in limine* submitted in *Booker v. Bard* solely for the purpose of preserving her rights on appeal, including Plaintiff's Motion in Limine No. 1 re FDA evidence (*Cisson* motion) [Doc. 9521].[1] However, Plaintiff asks that that the Court revisit Plaintiff's request for a limiting instruction with respect the FDA evidence and the 510(k) process. Specifically, as played out in the Booker trial, such an instruction is

[1] This submission addresses only Plaintiff's re-urged motions *in limine*. Plaintiff has not yet had an opportunity to review Bard's bases for re-urging various motion *in limine* rulings and reserves the right to address those upon review.

necessary in order to inform the jury appropriately regarding the FDA's role and actions with respect to medical devices, including IVC filters, that go through the 510(k) clearance process.

As a starting point, the design defect instruction to the jury pointed to the FDA evidence at three separate points: first, as one of the 13 factors (in fact, the thirteenth factor) that the jury could consider in determining whether the design was defective, the instructions pointed to a manufacturer's compliance with governmental standards. The same instruction also contained further instruction as to a manufacturer's compliance with regulatory standards (which is a part of Georgia's pattern instructions) and then a third reference that specifically that the jury could consider whether the FDA took regulatory action. Thus, the instructions heavily emphasize the role and actions of the FDA for the jury's consideration in determining whether the filter's design was defective.

A limiting instruction is appropriate to ameliorate the unduly prejudicial and confusing nature of the evidence when argued in the manner in which Bard argued FDA evidence in *Booker*. As an example, in *Booker*, Bard argued that FDA action (and inaction) was not only *a* factor, but essentially *the* factor:

> Let's talk about a document that I think addresses this issue head-on. ***What are the risks versus benefits of IVC filters?*** This was the document in 1996, before the retrievable filters were still on the market -- were even on the market, but addressing permanent filters and addressing IVC filters and deciding how to classify them. ***The FDA is looking at them.***
>
> And the exhibit is 5877.
>
> ***And the agency is explicitly weighing the risks and the benefits here of the IVC filters.*** And what does the agency say? The agency concludes that even though there are life-threatening risks associated with these devices, the disease that they are designed to treat, the disease state, deep vein thrombosis and PE, are life-threatening themselves. ***And the agency determines that the risks outweigh the benefits And the agency made this determination knowing about the very risks that occurred in this case.***
>
> The agency knew about filter migration, and even though the FDA knew that filters, in its view at that time, migrated 6 to 53 percent of the time, it was still willing to say that the benefits of these devices outweighed their risks. And with regard to fracture, the agency knew and says in that document, Exhibit 5877, that filters may fracture. That it's been reported at 2 percent of the time to occur. ***And despite knowing that, the agency determined that the benefits of IVC filters outweighed the risks. Why***

> ***would the FDA make that determination when risks such as those that unfortunately occurred with Ms. Booker can occur with these devices? It's because of the danger that we've heard about so much, a deep vein thrombosis and pulmonary embolism. These aren't minor conditions. These are life-threatening conditions.***

Booker Trial Tr. Mar. 29, 2018, at 2521:10-2522:17, Ex. A (emphasis added); *see also id.* at 2526:23-25 (FDA knew about caudal migration); 2527:25-2528:5 (FDA had Bard answer many questions).

Mr. North further repeatedly referenced the "clearance" of the G2 filter without any explanation that, as *Cisson* and other courts have clearly recognized, the 510(k) clearance process does not involve a determination of safety or effectiveness. *See id.* at 2537:6-2539:20 (arguing that Bard presented evidence regarding testing and complications to the FDA and yet were still cleared). Bard argued that it "complied with the FDA in the design and development of the G2, and that's an important factor under the law for you to consider when determining whether the design is defective." *Id.* at 2539:22-25.

In essence, Bard inappropriately urged the jury to defer to FDA's balancing of risks and benefits, substituting the FDA's judgment for the jury's considered deliberation based on the evidence presented at trial.[2] *See In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair System Products Liability Litigation*, 810 F.3d 913, 921–22 (4th Cir. 2016) ("*Cisson*") (discussing dangers of "wildly inflating the significance" of 510(k) clearance); *cf. Hangarter v. Provident Life and Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004) ("'an expert witness cannot give an opinion as to her *legal conclusion*, i.e., an opinion on an ultimate issue of law.' Similarly, instructing the jury as to the applicable law 'is the distinct and exclusive province' of the court.") (internal citations omitted).

[2] This is one explanation for why the Booker jury found, on the one hand, no design or warning strict liability defect with the G2, and, on the other hand, that Bard was negligent in failure to warn about the dangers of the G2 and, by clear and convincing evidence, that plaintiff was entitled to punitive damages for Bard's egregious conduct in failing to warn of the dangers of its device.

Given the emphasis in the instructions on regulatory action and the FDA and to protect against undue emphasis on FDA evidence in the jury's deliberations, Plaintiff requests a limiting instruction to the following effect (as previously proposed in Booker):

FDA Limiting Instruction

> The 510(k) process focuses on device equivalence, not device safety.
>
> Bard's IVC filters are not FDA approved, they are cleared by the FDA through the 510(k) premarket notification process.
>
> Clearance of a device through the 510(k) process does not render a finding by the FDA that the filter is safe and effective.
>
> Any representation that creates an impression of official approval of a device because the manufacturer complied with the 510(k) premarket notification regulation is misleading and constitutes misbranding.

Source: January 29, 2018, Order [Doc. 9881]; 21 C.F.R. § 807.97.

For these reasons, Plaintiff respectfully requests the Court give a limiting instruction to the jury concerning FDA evidence.

RESPECTFULLY SUBMITTED this 10th day of April 2018.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark S. O'Connor*
Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liason Counsel for Plaintiffs Doris and Alfred Jones

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of April, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine